

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-631V

Filed: February 23, 2015

(Not to be published)

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DOUGLAS ORTON	*	
as Personal Representative of the Estate of,	*	
WALTER J ORTON, III	*	
	*	
Petitioner,	*	Ruling on Record; Influenza Vaccine;
v.	*	numbness, tingling, fingertips; parathesias;
	*	unsteady gait; Guillain-Barré syndrome
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

* * * * *

Diana Stadelnikas Sedar, Esq., Maglio Christopher and Toale, PA, Sarasota, FL for petitioner.
Gordon E. Shemin, Esq., United States Department of Justice, Washington, DC for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION¹

Gowen, Special Master:

On August 30, 2013, Douglas Orton filed a petition as personal representative of the estate of Walter J. Orton, III under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 *et seq.* (2006) (“Vaccine Act”). Petition at Preamble. Petitioner alleged that Walter J. Orton, III (“Mr. Orton” or “the decedent”) received an influenza (“flu”) vaccine on October 3, 2011, and as a result developed Guillain-Barré syndrome (“GBS”) three days later. *Id.* at ¶ 4. The petition further alleges that Mr. Orton’s course of GBS progressed rapidly and that on October 23, 2011 he suffered complete respiratory arrest and passed away after failed resuscitation efforts. *Id.* at 6.

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 and note (2006)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information, that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

On December 4, 2014, petitioner filed a motion for a ruling on the record. *See* Petitioner's Motion for Decision on the Record ("Motion"). Respondent filed a response to petitioner's motion on December 22, 2014. *See* Response to Petitioner's Motion for Decision on the Record ("Resp.").

The undersigned finds that petitioner has not satisfied his burden of proof as required in an off-Table claim, and thus is not entitled to compensation.

I. Procedural Background

Petitioner filed an affidavit and medical records from several treating physicians in support of the petition. *See* Petitioner's Exhibits ("Pet. Ex(s.)") 1-10. On December 16, 2013, respondent filed a Rule 4(c) Report in which she concludes compensation is not appropriate in this case. On May 7, 2014, the undersigned ordered petitioner to file an expert report addressing the *Althen*² criteria, particularly, whether it is medically appropriate to infer vaccine causation when the onset of the decedent's GBS occurred within a day, or several days, of receipt of the flu vaccination. *See* Scheduling Order, docket no. 21. Petitioner was granted two motions for extension of time to file an expert report. On December 4, 2014, in lieu of an expert report, petitioner filed a motion for a decision on the record. Respondent filed a response, thus making this case ripe for a decision.

II. Factual History

Mr. Orton was eighty-four years old when he received a flu vaccination on October 3, 2011. Pet. Ex. 1 at 1. His prior medical history was significant for prostate cancer that was successfully treated with radiation, non-insulin dependent diabetes, cataract surgery, and a left knee replacement surgery. Pet. ex. 2 at 2; pet. ex. 6 at 27. Two days after receiving a flu vaccine, Mr. Orton presented to the emergency department at Millard Fillmore Gates Hospital in Buffalo, New York complaining of paresthesias³ at the tips of his fingers on both hands, and an unsteady gait. *Id.* at 13. The initial impression at the emergency room was that he was experiencing a non-hemorrhagic cerebral vascular event. *Id.* at 14. Mr. Orton was discharged home with a consultation order to complete an acute stroke study and an MRI. *Id.* at 16.

A neurology consultation note on October 6, 2011 places the onset of Mr. Orton's symptoms of paresthesias and difficulty walking just one day after receipt of a flu vaccine. *Id.* at 36. An MRI of the brain was unremarkable, however the treating neurologist, Dr. Shakeel, suspected GBS. *Id.* at 41. Dr. Shakeel recommended that Mr. Orton be admitted to the hospital for IVIG treatment, close observation of his respiratory status due to decreasing FVC⁴ values, and further consideration of a lumbar puncture procedure to be completed after seven days from the onset of symptoms. *Id.*

Upon admission to the hospital, Mr. Orton's course of GBS progressed rapidly. On October

² *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

³ "An abnormal touch sensation, such as burning, prickling or formication, often in the absence of an external stimulus." *Dorland's Illustrated Medical Dictionary* 1371 (30th ed. 2003).

⁴ Or, Forced Vital Capacity, is a measurement of lung function. *Topic Overview*, WEBMD (Feb. 20, 2015), <http://www.webmd.com/lung/tc/forced-expiratory-volume-and-forced-vital-capacity-topic-overview>.

7, 2011, he was transferred to the Intensive Care Unit and electively intubated. *Id.* A five-day course of IVIG⁵ treatment resulted in no significant improvement. *Id.* at 375. A lumbar puncture performed on October 10, 2011 was negative for malignancy. *Id.* at 147. Five cycles of plasmapharesis,⁶ which were completed by October 21, 2011, resulted in some improvement in his motor strength; however, he still required full ventilator support. *Id.* at 442. Sadly, on October 23, 2011, Mr. Orton went into heart failure and died. Pet. Ex. 6 at 453.

Petitioner's exhibit 9 is a death certificate which lists the immediate cause of death as asystole due to ventricular tachycardia.⁷ Pet. Ex. 9 at 1. GBS was listed as one of several "significant conditions contributing to [Mr. Orton's] death." Pet. Ex. 9 at 1.

III. Summary of the Parties' Arguments

Petitioner has submitted his case for a decision on the medical records alone, without offering an expert report to set forth a reliable medical theory of causation or to explain a logical sequence of cause and effect showing that the vaccine in question was the cause of the alleged injury and death. *See Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Neither has petitioner submitted evidence addressing a medically appropriate timeframe, as is also required under *Althen*. Petitioner avers that "[a]fter further analysis of the medical records, science and expert consultation, [he] will not be filing a medical expert opinion" and would like a decision to be made on the record as it stands. Motion at ¶ 8.

Respondent contends that petitioner has failed to meet his burden of proof, as he has not provided sufficient evidence to establish a more likely than not causal connection between Mr. Orton's receipt of the flu vaccine on October 3, 2011, and the onset of his GBS within twenty-four hours. Resp. at 1-2. Respondent further contends that petitioner has not provided a medical expert report that advances a theory on causation, a logical sequence of cause and effect, or a medically appropriate timeframe for the onset of Mr. Orton's GBS and the flu vaccine at issue here. Resp. at 1-2. Respondent asks the Court to deny petitioner's claim and dismiss the petition accordingly. Resp. at 2.

IV. Analysis

a. Applicable Legal Standard

In order to prevail under the Program, petitioner must prove either a "Table" injury⁸ or that a vaccine listed on the Vaccine Table was the cause-in-fact of an injury. Based on the record as

⁵ Intravenous immunoglobulin is a blood product used to treat immune deficiency. *Intravenous Immunoglobulin*, MEDSCAPE (Feb. 20, 2015), <http://emedicine.medscape.com/article/210367-overview>.

⁶ "The removal of plasma from withdrawn blood, with re-transfusion of the replaced plasma into the donor." Dorland's Illustrated Medical Dictionary 1446 (30th ed. 2003).

⁷ Asystole is the absence of heartbeat. *Id.* at 170.

⁸ A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified.

a whole, the undersigned finds that petitioner has not established that Mr. Orton suffered a Table injury, as GBS is not an injury listed on the Vaccine Table. Therefore, petitioner must prove that the influenza vaccine caused-in-fact the alleged injury.

The Vaccine Act provides that a special master may not make a finding awarding compensation based on the claims of petitioner alone, unsubstantiated by medical records or medical opinion. *See* § 13(a)(1). To satisfy his burden of proving causation-in-fact in this case, petitioner must “show by preponderant evidence that the vaccination brought about [the decedent’s] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Althen v. Sec’y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also Hines v. Sec’y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). He must show “that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.” *Grant v. Sec’y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Circumstantial evidence and medical opinions may be sufficient to satisfy the *Althen* prongs. *Capizzano v. Sec’y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). However, mere temporal association is not sufficient to prove causation in fact. *See Grant v. Sec’y of HHS*, 956 F.2d 1144, 1147 (Fed. Cir. 1992).

When a petitioner alleges an “off-Table” injury, eligibility for compensation is established when the petitioner demonstrates, by a preponderance of the evidence, that: (1) a vaccine set forth on the Vaccine Injury Table was received; (2) the vaccine was received in the United States; (3) the person in question sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months or resulted in death. *See* § 11(c).

Petitioner has established that the decedent did receive a covered vaccine under the Vaccine Injury Table and that it was received in the United States. *See* Pet. Ex. 1 at 2. However, petitioner has failed to establish that the decedent’s GBS, and ultimately his death, was caused by the flu vaccination at issue.

b. *Althen* Prong One

Under the first prong of *Althen*, petitioner is required to set forth a reliable medical theory that explains how a particular vaccination can cause the injury in question. *Althen*, 418 F.3d at 1279. Scientific certainty is not required to establish causation under the Vaccine Act. *Id.* at 1280 (holding that the purpose of the Vaccine Act’s preponderance of the evidence standard “is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body”). However, a causation theory or mechanism must be proposed and supported by a sound and reliable medical or scientific explanation. *Knudsen v. Sec’y, HHS*, 35 F.3d 543, 548 (Fed Cir. 1994).

In this case, petitioner has failed to proffer a theory explaining how the flu vaccine can cause GBS resulting in death. Without a medical theory to elucidate the circumstances by which a vaccine can cause a particular injury, there is hardly a basis to form a decision on causation. Especially when, as in the case here, the decedent’s medical records raise questions bearing on

causation. For example, respondent has submitted that the onset of Mr. Orton's GBS was within one day, which respondent contends, is "too short a time period to be medically appropriate to infer vaccine causation." *See* Respondent's Report at 4. Petitioner has not provided an expert opinion to indicate why an earlier onset would be reasonable in this case, which would be most helpful in resolving this question and others raised by the record. As petitioner has not provided a theory to preponderate the evidence in his favor, *Althen* prong one fails.

c. Althen Prong Two

The second *Althen* prong requires petitioner to establish that the vaccine was the reason for the injury—not only a but-for cause of the injury but also a substantial factor in bringing about the injury. *See Shyface v. Sec'y of HHS*, 164 F.3d 1344, 1352 (Fed. Cir. 1999). Impressions from treating physicians can be probative when evaluating the second *Althen* factor, as "treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano v. Sec'y of HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006).

However, in this case, although several of Mr. Orton's treating physicians attributed his GBS to the flu vaccination, *see, e.g.*, pet. ex. 6 at 46, 54, 244 and pet. ex. 7 at 215, 218, none provided an explanation of how receipt of the vaccine specifically caused the decedent's GBS and ultimate death. To prove causation under this prong, there must be more than a mere possibility of a connection. Here, the statements of the decedent's treating physicians do not go as far as to provide an explanation of a causal relationship, but merely make note of a temporal relationship between the vaccination and onset of symptoms, or at most, suggest a *possible* connection. Where treating physicians simply indicate "an awareness of a temporal, not causal relationship[.]" a special master may decline to afford significant weight to those statements. *Cedillo v. Sec'y of HHS*, 617 F.3d 1328, 1347 (Fed. Cir. 2010). Accordingly, the undersigned finds the weight of Mr. Orton's treating physicians do not provide a sufficient basis to rule in favor of petitioner on *Althen* prong two.

d. Althen Prong Three

The third *Althen* prong requires the petitioner to demonstrate that the injury "occurred within a medically acceptable time frame." *Pafford v. Sec'y of HHS*, 451 F.3d 1352, 1358 (Fed. Cir. 2006). Petitioner must establish a proximate temporal relationship, which "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The appropriateness of timing of the onset of symptoms is fairly specific to the diagnosis and the alleged vaccine.

As discussed above, respondent raises the issue of a rapid onset of symptoms of GBS. While it may be medically acceptable in Mr. Orton's case for the onset of symptoms of GBS to occur within one day of receipt of a flu vaccine, the undersigned fact-finder cannot aptly decide the issue without a medical opinion explaining how the vaccine could trigger the initial symptoms of GBS within one day. Accordingly, petitioner has failed to meet his burden under *Althen* prong three.

V. Conclusion

The medical records do not provide adequate support for, or an explanation of, a medical theory to explain the decedent's death as allegedly caused by GBS. Although petitioner's treating physicians noted a temporal relationship between the decedent's flu vaccination and GBS, they did not provide an opinion as to a causal relationship. Moreover, an appropriate medical timeframe to infer vaccine causation is in dispute. The undersigned finds that petitioner has failed to meet his burden under all three of the *Althen* prongs and the case must be dismissed.

The Clerk shall enter judgment accordingly.⁹

s/ Thomas L. Gowen

Thomas L. Gowen
Special Master

⁹ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.